

Notice of Allowability

Application No.

10/077,489

Examiner

Anne Marie S. Wehbe

Applicant(s)

RIJSEWIJK ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment received on 12/23/03.
2. ☒ The allowed claim(s) is/are 16-20,22-24,26-40,42,43,45-59,61,62,64-66 and 68-107.
3. ☒ The drawings filed on 15 February 2002 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/232,469.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Anne Marie Yvonne on 3/23/04.

The application has been amended as follows:

1. In claim 16, line 5, the phrase -- operably linked to a eukaryotic promoter -- has been inserted after the word "pathogen".
2. In claims 17, line 4, the phrase -- operably linked to a eukaryotic promoter -- has been inserted after the word "pathogen".
3. In claim 36, line 4, the phrase -- operably linked to a eukaryotic promoter -- has been inserted after the word "pathogen".

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4. In claim 37, line 3, the phrase -- operably linked to a eukaryotic promoter -- has been inserted after the word "pathogen".

5. In claim 56, line 7, the phrase -- operably linked to a eukaryotic promoter -- has been inserted after the word "pathogen".

6. Claims 21, 25, 41, 44, and 60 have been canceled.

The following is an examiner's statement of reasons for allowance. The rejection of claims pending claims 16-20, 22-24, 26-40, 42-43, 45-59, 61-62, and 64-66 under 35 U.S.C. 112, first paragraph, has been withdrawn in view of applicant's arguments and supporting evidence of record for the use of strong eukaryotic promoters other than the CMV promoter in the claimed immunogenic compositions. As noted by the applicants, the specification teaches the use of "strong eukaryotic promoter, i.e. CMV promoter" in the specification on page 7. The working examples also exemplify the use of plasmids which comprise a nucleic acid sequence encoding an immunogen of a bovine pathogen operably linked to the CMV promoter. The applicant has further submitted evidence in the form of reference by Donnelly et al. that demonstrates that other strong eukaryotic promoters were known in the prior art to be capable of expressing immunogenic amounts of antigen from a plasmid vector following administration *in vivo*. Finally, the applicant's argument that it is not necessary to specifically disclose or exemplify a large number of operative embodiments to outweigh the possibility of some inoperative embodiments has been found persuasive.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a stylized flourish at the end.